

**REMARKS**

Reconsideration of the present claims is hereby requested.

Claims 19, 22, 23, 30-34, 36-38, 40, 43-48, 50, 53-54, 61-65, 67-69, 71, and 74-79, which are all of the pending claims, stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,551,419 to Froehlich et al. ("Froehlich") in view of U.S. Patent No. 5,704,345 to Berthon Jones ("Berthon-Jones") and U.S. Publication No. 2002/0088465 to Hill ("Hill"). In response, no claims are being amended, added, or cancelled.

The present invention is directed to concurrently overcoming two completely different breathing abnormalities during delivery of CPAP therapy to a patient, where the CPAP therapy is delivered according to a pressure-time template. The approach involves determining the presence of two events, where the first event is a particular type of breathing episode, such as an apnea, and the second event is flow flattening. The claims include delivering a first pressure in synchrony with a transition and based on the first event as well as delivering a second pressure in synchrony with a transition and based on the second event. Various data may be collected and one set of data is used to determine the first event and different data are used to determine the second event. In the present invention IPAP is reset from that in the pressure-time template based on a data set used for detecting an apnea and EPAP is reset from that in the pressure-time template based on a different data set used for detecting flow flattening. This method is not disclosed or suggested by any of the three references.

The independent claims (claims 19, 34, 50, and 65) are directed to methods and apparatus which include a controlled blower. The control of the blower is key to the claims and is distinct from any disclosure or suggestion in the cited references. Several elements of the independent claims in combination are distinguishable from the cited references, including:

- Initially applying a pressure-time template to a patient in synchrony with the patient's breathing cycle. To apply the template in synchrony, the controller must sense the patient's breathing cycle, including transitions. The references do not disclose or suggest applying a pressure-time template, identifying transitions in the patient's breathing cycle, or applying a pressure-time template in synchrony with patient breathing.
- Based on the sensed pressure and/or sensed flow signals, determining the presence of an event, such as an apnea, a hypopnea, or a snore. Although not expressly articulated in the claims, this event is indicative of a first breathing abnormality - a patient's sudden breathing restriction, possibly caused by the sudden presence of an obstruction.
- Determining the presence of a flow flattening event from sensed data. Although not expressly articulated in the claims, flow flattening is an indication of a reduction in air intake by the patient.
- The controller adjusts the pressure-time template by controlling a first delivered pressure, delivered in synchrony with a first transition, and

determined based upon the first event. None of the references discloses such an adjustment to an in-place pressure-time template.

- The controller also adjusts the pressure-time template by controlling a second pressure, delivered in synchrony with a second transition, and determined based upon the second event. None of the references discloses such an adjustment to an in-place pressure-time template.

All of the claims include these limitations. Importantly, the approach in the claims is used so as to potentially provide the patient with concurrent solutions to two different problems – cessation or near cessation of breathing, as well as an increasing limitation of flow during inhalation (so called flow flattening).

Notably, each of the two events (such as an apnea or flow flattening) is determined independently from the other and each is a different sleep disordered breathing events. These two determined events are used to set two different pressure treatment levels for treating a patient, each set independently of the other. The cited references either set one treatment level or set two treatment levels based upon a single-sourced event, and none of the references is directed to independently setting two parameters based on two different sleep disordered breathing conditions.

In particular, the present Office Action cites to three different references, each for different reasons. Froehlich is relied upon for disclosing a CPAP apparatus and for disclosing controlling the blower by automatically determining and treating the presence of sleep disordered breathing and determining sleep disordered breathing

such as apnea from known techniques, but that alone is not the present invention. Berthon-Jones is relied upon for determining the presence of an apnea by calculating indices and for disclosing an index for both an apnea and flow flattening. However, Berthon-Jones does not set two pressure points at all, let alone independently. Hill is relied upon for varying IPAP and EPAP to counter a single sleep disordered breathing event. Also, there is no suggestion in any of the references to combine with any of the others, and none of the references suggests concurrent adjustment of a pressure-time template for two separate problems, with those adjustments being based on different independent measures. Further, none of the references are directed to concurrently overcoming two different and distinct patient breathing problems during the course of CPAP therapy delivery, and certainly not to the methods of the claims described in these remarks.

In addition, the basis of the 103 rejection appears to be an aggregation of various elements from different references which appear in isolation and concluding that the present invention is subsequently obvious. However, none of the references is directed to solving the problem being solved with this invention, none of the references includes a suggestion directed to solving the present problem, none of the references includes a suggestion to combine with the other references, and, even when aggregating the various references, some elements remain undisclosed by the references.

Applicants also express appreciation to the Examiner for the detailed "Response to Arguments" included in the present Office Action. Four full paragraphs are included in that section and each is discussed in turn below.

1. Determining an index is not suggestive of determining a particular event, such as an apnea. The comment in the first paragraph under "Responses to Arguments" appears to be based on the change from "index" to "event" in the claims in an earlier amendment. First, Applicants indicated that determining an actual event is something distinct from an index. An index is a calculation often compared to a threshold, whereas in the present claims, there is no discussion of an index, only discussion of the occurrence of an "event". Even so, the "indices" of Froehlich are not the present invention and the other elements of the invention articulated above remain distinguishable.

2. Setting two pressure points based on one measured parameter is not suggestive of setting two pressure points each based on a different measured. The Office Action suggests that Berthon-Jones determines two disordered breathing events from different characteristics of a flow signal. However, Berthon-Jones is directed to solving a completely different problem than the problem of the present invention, and Berthon-Jones' problem would not lead one to the present solution. Berthon-Jones is merely directed to "determining the occurrence of an apnea, patentcy, and/or partial obstruction" and not to overcoming a combination of potential breathing difficulties (see Abstract). In Berthon-Jones, there is no need to

seek a second independent measure to determine an apnea, just as a single measure is sufficient in the present invention.

3. None of the references even suggests using one parameter to set one pressure point and a second parameter to set a different pressure point. The Remarks in the third paragraph that suggest that because "the indices of Berthon-Jones and Hill could be combined into a single signal or two separate ones since the same information is being determined in each" misses the point of the invention. First, in the present invention two different signals, reflecting different sources of data, are used, but each is used for a completely different reason and neither of the reasons are disclosed or suggested in Berthon-Jones or either of the other references.

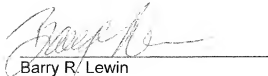
4. Hill's disclosure that sleep apnea has been treated is not tantamount to disclosing or suggesting the methods and apparatus of the present claims. This paragraph appears to be based on Applicants' earlier comment that Hill is directed to treating patients with CSR. However, Applicants' point is that the present invention is directed to treating multiple conditions, where one of the conditions is sleep apnea and Hill is not directed to either treating sleep apnea or multiple conditions.

One other point regarding a comment in the last four lines of page 4 of the present Office Action. The Office Action states that "there is nothing structurally in Froehlich that would prevent the controller from adjusting both the EPAP and IPAP based on the separate events/indices." However, not precluding an invention is not the same as disclosing or suggesting it.

For the reasons described above, none of Berthon-Jones, Froehlich, or Hill, either alone or in combination, disclose or suggest claims 19, 34, 50, 65, or the claims which depend upon them. The early passage to issue of the application is respectfully requested.

If any additional fee is required, the Commissioner is hereby authorized to charge the amount of any such fee to Deposit Account No. 07-1730, Docket No. 3869-038.

Respectfully submitted,  
**GOTTLIEB, RACKMAN & REISMAN**

A handwritten signature in blue ink, appearing to read "Barry R. Lewin", is written over a horizontal line.

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